TABLE OF CONTENTS

ON-SITE ASSESSOR
INSTRUCTIONAL MANUAL

CHAPTER 1
INTRODUCTION

1.1 Purpose

The Assessor Training Manual presents the principles and practices associated with conducting a laboratory on-site assessment as conceptualized by the National Environmental Laboratory Accreditation Conference (NELAC) standards. The manual is based on relevant portions of the NELAC standards for laboratory accreditation.[1] The principles and practices described herein must be used by all on-site assessors representing environmental laboratory accrediting authorities that are recognized by the National Environmental Laboratory Accreditation Program (NELAP).

This manual serves two principal purposes:

1. It, along with the approved standards, represents a major component of the course text for the NELAC Basic Assessor Training Course.
2. It is an up-to-date reference manual for laboratory assessors.

As such, its primary benefit is to help ensure a level of national consistency in NELAC on-site assessments on a continuing basis.

The manual serves numerous other purposes as well. For example, it:

- Provides guidance for maintaining appropriate records and documentation of the on-site assessment process so that all assessment findings are fully traceable and can be meaningfully reviewed and evaluated in the event of a dispute;
- Provides guidance that will enable the on-site assessment process to be as efficient as possible;
- Provides guidance as to the duties and responsibilities of all on-site assessment personnel throughout the assessment process and within the framework of the NELAP accreditation process, and
- Provides a tool for laboratory personnel so that they can be well-prepared for assessments and participate fully in the assessment process.

It is a goal of NELAP to ensure that all on-site assessment personnel achieve a uniformly high standard of performance. This manual and the accompanying basic training course and related

[1]This version of the manual reflects the draft NELAC standards as of July 3, 1997. Each year at their annual meeting, the members of NELAC consider modifications to the standards and, following the annual meeting, the standards are revised to reflect any changes adopted by the Conference. This manual will be updated annually, as necessary, to reflect any changes to the standards made by the Conference.

training materials are the principal tools to be used in fulfilling that goal.

1.2 Organization

The remainder of this manual consists of four additional chapters:

- **Chapter 2, NELAC Overview,** provides a brief overview of the laboratory accreditation standards and how each relates to the assessment process.
- **Chapter 3, Quality Systems,** provides the assessor guidance for determining compliance with Chapter 5 (Quality Systems) of the NELAC standards and must be used in conjunction with Chapter 5 of the NELAC standards and the associated NELAC checklists. The guidance provided in Chapter 3 is focused upon how to evaluate compliance rather than to document an exhaustive listing of items to assess.
- **Chapter 4, Basic Auditing Skills,** familiarizes the assessor with the fundamental skills, techniques and ethics associated with auditing.
- **Chapter 5, Assessment Principles and Practices,** provides general information regarding the principles and practices that must be followed while conducting assessments as an assessor employed by or under contract with a NELAP-approved accrediting authority.

The Assessor Training Manual is organized to reflect the NELAC standards and frequent references to specific sections of the standards are made throughout the document. It is the responsibility of each assessor and/or training provider using the Assessor Training Manual and the NELAC standards and checklists to ensure that they are referencing the most recent versions of the documents. Assessors and/or training providers must determine whether the versions that they are using take into account the changes, if any, as approved by the NELAC voting membership at the most recent annual Conference. The current versions of the NELAC standards, the Assessor Training Manual and the NELAC checklists are available on-line through the NELAC Home Page at http://ttnwww.rtpnc.epa.gov/html/nelac/nelac.htm within ninety (90) days after each annual Conference.

CHAPTER 2
NELAC OVERVIEW

2.0 Purpose

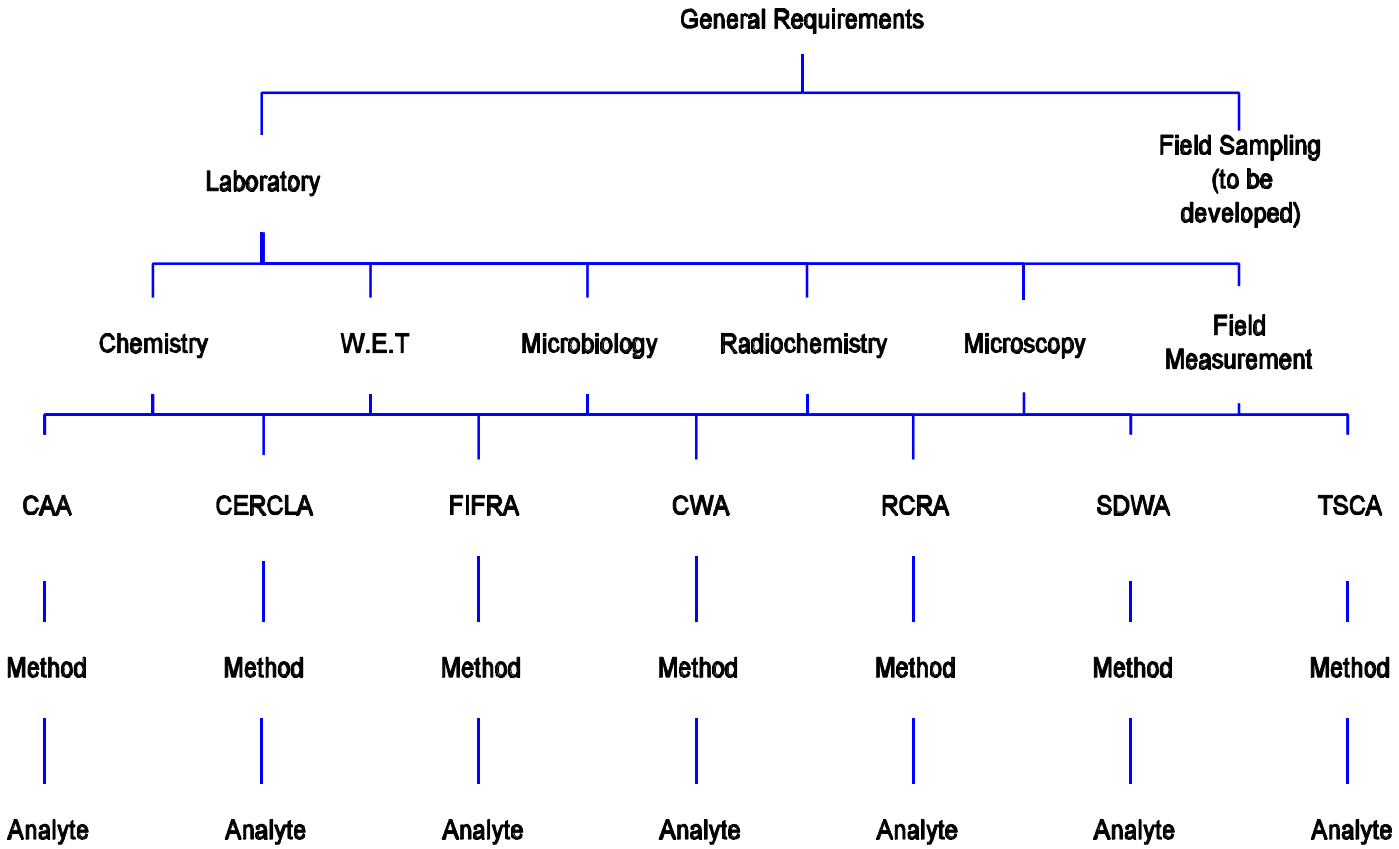
The information in this Chapter is presented for the purpose of training on-site assessors. The information is not intended to be a detailed description of the NELAC standards, but to give an overview of the laboratory accreditation standards. While the synopses presented below are believed to be consistent with the standards, the actual approved NELAC standards take precedence over the information presented in this Chapter. On-site assessors must consult the most recent approved version of NELAC approved standard for specific information related to each standard.

2.1 Program Policy and Structure (NELAC Standard, Chapter 1)

The Program Policy and Structure Committee is responsible for developing and maintaining the Constitution and By-Laws, and the Policy and Structure Chapter of the NELAC standards. The process for considering, revising and approving changes to the standards is described in Chapter 1, Policy and Structure, of the NELAC standards. The NELAC is a voluntary organization of state and federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories. Therefore, NELAC is a standards setting body and has no authority to implement a laboratory accreditation program. Laboratory accreditation programs are implemented and administered by state and federal accrediting authorities. State and federal accrediting authorities which adopt and are recognized as conforming to the NELAC laboratory accrediting standards are part of the National Environmental Laboratory Accreditation Program (NELAP). The NELAP is staffed and administered by EPA.

The NELAC Policy and Structure standard describes the scope of the NELAP program. This is particularly important to on-site assessors who must understand the scope and application of the NELAC standards and National Environmental Laboratory Accreditation Program to effectively assess laboratory conformance to the standards.

The NELAC standards are designed to apply to laboratories generating environmental data where such data is mandated by EPA statutes and regulations. The Policy and Structure standard describes the accreditation requirements as a tiered approach (see Figure 2-1). The first tier consists of general quality systems requirements found in the NELAC Quality Systems standard. The second tier consists of either laboratory or field testing. The third tier consists of chemistry, whole effluent toxicity, microbiology, radiochemistry, microscopy and field measurements. The fourth tier consists of the various EPA regulatory programs shown in Figure 2-1.



This figure and the supporting text will be reviewed at a later date to accomodate the unique characteristics of the GLP program, taking into consideration the recommendations of the Environmental Laboratory Advisory Board.

Figure 2-1. NELAC Tiered Scope of Accreditation

Prior to conducting the on-site assessment, the assessment team must have a clear understanding of the fields of testing for which the laboratory is applying. This information should be available in the laboratory's application for accreditation or renewal of accreditation. The application for accreditation will be provided to the assessor by the accrediting authority. The full process for defining the scope of accreditation is described in section 5.2.1 of this manual.

2.2 Accrediting Authority (NELAC Standard, Chapter 6)

The Accrediting Authority Committee is responsible for developing and maintaining the Accrediting Authority Chapter of the NELAC standards. This chapter establishes the process and criteria by which state and federal accrediting authorities are determined to be in conformance with the NELAC laboratory accrediting standards and are recognized as members of the National Environmental Laboratory Accreditation Program. On-site assessors should be familiar with the process by which accrediting authorities are granted NELAP recognition. This information is not necessarily required to perform an on-site assessment of a laboratory, but will help the assessor to understand the overall NELAP process.

The Accrediting Authority standard establishes a process by which those state and federal organizations wishing to gain NELAP recognition apply to EPA's NELAP office. After a completeness review by the NELAP office, the application is referred to a NELAP assessment team for a technical assessment. For initial applications, the NELAP assessment team conducts an on-site audit of the candidate accrediting authority. On-site audits of the accrediting authority are conducted upon initial application and every four years thereafter by the assessment team. When the on-site audit is completed, the assessment team issues an audit report noting any deficiencies observed. After allowing for resolution of any deficiencies, the assessment team will make a recommendation to the NELAP director to grant, maintain or revoke NELAP recognition to the candidate accrediting authority. The NELAP Director has the option of accepting or rejecting the assessment team's recommendation.

The standard also provides technical requirements which accrediting authorities must meet to receive NELAP recognition. While all the requirements are not included here, some of the elements required of the accrediting authority include:

- the authority to carry out a laboratory accreditation program,
- a system to evaluate the performance of laboratory assessors,
- a designated individual to manage the accreditation program,
- arrangements to avoid conflict of interest for accreditation staff,
- a documented quality system which includes internal audits,
- standard operating procedures for dealing with appeals, disputes and complaints related to laboratory accreditation, and,
- requirements for laboratories to participate in a proficiency testing program.

2.3 Accreditation Process (NELAC Standard, Chapter 4)

The Accreditation Process Committee is responsible for developing and maintaining the Accreditation Process Chapter of the NELAC standards. This chapter establishes the process and criteria by which laboratories apply to a state or federal accrediting authority and obtain NELAP accreditation. It is particularly important that the on-site laboratory assessor is familiar with and understands this section of the NELAC standard. The on-site assessor will be involved with many of the steps required of laboratories in the accreditation process.

The components of the accreditation process include personnel qualifications, on-site assessment, proficiency testing, and quality system. Laboratories must meet the requirements in each of these areas in order to be NELAP accredited. The requirements for laboratories seeking accreditation are also covered in detail in various sections of the NELAC standards, including Chapter 2, Proficiency Testing; Chapter 3, On-site Assessment; and Chapter 5, Quality Systems. However, the Accreditation Process standard gives an overview of some of these requirements. The accreditation process begins with a laboratory's application to the accrediting authority. After receiving the application and determining whether it is adequate, the accrediting authority is responsible for assigning an on-site assessment team to conduct the laboratory evaluation. The assessment team may consist of one or more assessors depending on the scope of accreditation to be conducted. When the on-site assessment is completed, the assessment team issues an assessment report noting any deficiencies observed. After allowing for resolution of any deficiencies with the laboratory, the accrediting authority will make the decision to award, deny, suspend or revoke NELAP accreditation.

In addition to the on-site assessment process, the standard requires the laboratory to have a responsible party of record. The responsible party of record is a full-time member of an environmental laboratory who exercises day-to-day supervision of the laboratory procedures and reporting of results. On-site assessors will be responsible for evaluating the qualifications of the laboratory responsible party of record. Assessors should also be aware that the Accreditation Process standard provides for a waiver of the responsible party of record qualifications provided the laboratory meets NELAC proficiency testing and quality control requirements. This waiver is in effect provided the responsible party of record is employed by the laboratory on the date the laboratory becomes subject to NELAC standards. Additional general requirements for laboratory staff are found in the NELAC Quality Systems standard. Assessors should be aware that the Quality Systems personnel requirements are generic rather than prescriptive.

The Accreditation Process standard requires a laboratory to meet the following requirements with respect to proficiency testing (PT):

- upon initial application, successful analysis of two sets of PT samples, at least 30 days apart,
- analysis of one PT sample twice per year in each field of testing (program-matrix-analyte),

and,

- a history of at least two passing results out of the most recent three PT samples analyzed for each field of testing.

The on-site assessor should refer to the Accreditation Process standard for additional details.

2.4 Proficiency Testing (NELAC Standard, Chapter 2)

The Proficiency Testing Committee is responsible for developing and maintaining the Proficiency Testing Chapter of the NELAC standards. This PT standard establishes the procedures and criteria by which laboratories seeking to be accredited must obtain, analyze, and score on PT samples. It also establishes the process and criteria by which organizations providing PT samples are approved by a proficiency testing oversight body. The major components of the PT program include:

- multiple PT providers meeting stringent criteria,
- specific criteria for the design of PT samples and studies,
- defined pass/fail criteria for evaluating PT sample results,
- initial approval and on-going oversight of PT providers by a proficiency testing oversight body, and,
- specific requirements for laboratories participating in PT studies.

On-site assessors will not be involved in the approval of PT providers. However, assessors should be aware that the PT standard requires laboratories to participate in a PT study conducted by an approved provider. Monitoring of a laboratory's PT study results will usually be performed by the accrediting authority. The on-site assessor must be cognizant of the laboratory PT requirements given in section 2.3 of this manual and in Chapters 2 and 4 of the NELAC standards. Assessors must also be aware that laboratories are required to handle the PT sample analyses in the same manner that it performs analysis for real environmental samples to the extent possible. Prior to the completion of a particular PT study, laboratories are restricted from:

- exchanging PT sample results with other laboratories,
- submitting NELAC PT samples to another laboratory for analysis,
- knowingly receiving and analyzing a NELAC PT sample from another lab, and,
- attempting to obtain the target value of a PT sample from the provider.

If, during an on-site assessment, the assessor becomes aware that the laboratory has violated any of the above restrictions, the facts must be reported to the accrediting authority and included in the on-site assessment report. It is highly recommended that assessors include reviews of PT sample analyses in the data audits conducted during the on-site assessment.

CHAPTER 3
QUALITY SYSTEMS

3.1 ORGANIZATION AND MANAGEMENT

3.1.1 Legal Identity

For legal purposes, it is critical that the laboratory can be verified as a legal entity during the assessment. The laboratory director (however named) must be able to produce a taxpayer identification number or federal employer identification number.

3.1.2 Organization and Responsibilities

The organization and management of the laboratory should be assessed vs. the laboratory's application for accreditation, quality assurance manual, and an organization chart that diagrams the laboratory's reporting structure, lines of reporting, and communication. The assessor should verify that there are no discrepancies between these documents, that there are current, written job descriptions for those responsible for laboratory management and laboratory activities, and that there are defined "back-ups" for key responsibilities.

Job titles will vary among organizations, but there should be job descriptions for (1) the individual who has overall responsibility for the operation of the laboratory and data quality, (2) the individual who directs and oversees activities in the analytical laboratory, (3) the principle analysts for each field of testing, (4) the person responsible for performing quality assurance activities, and (5) any other staff that are identified in key laboratory roles.

3.1.3 Supervision of staff

Laboratory staff working "at the bench" or performing analyses must be experienced before working without direct supervision. The degree of supervision required and independence allowed in decision-making will vary considerably with the field of testing. However, the laboratory should have routine procedures for determining when staff are qualified to work independently, without direct supervision. The assessor should verify for selected staff that the qualifications for independent analysis have been met. The assessor should also assess that the ratio of supervisory to non-supervisory staff is "adequate". No ratios are defined for the purpose of assessment; the assessor will likely be aware of supervision problems if (1) one person is constantly named by staff during interviews, (2) that one person is constantly interrupted during the assessment, or (3) the organization chart shows many staff reporting to one person with no indication that responsibilities are divided among other senior staff.

3.1.4 Conflict of Interest

It is appropriate to ask the laboratory director (however named) to describe policies for avoiding

any potential conflict of interest by the laboratory or its employees. The assessor should ask if there are written procedures in place for avoiding potential conflict of interest and how compliance with these procedures are monitored by the laboratory. The assessor should request a copy of any such policy or other supporting documents and should verify during subsequent interviews with staff at the project management level that the policies are implemented routinely.

The assessor should also verify that the laboratory has developed a plan to protect client confidentiality. Staff interviews may be the best method of verifying that the policy is implemented.

3.1.5 Independent Reporting

The laboratory must have in place a system of analysis and reporting that ensures unbiased data reporting. Analysts must be free to report all data results obtained by approved analytical methods without consideration of the sample source. The laboratory must have some method of independent review that assesses data quality based on instrument performance, calibration, and quality control results. The assessor may find the description of data reviews and data reporting procedures in the laboratory QA manual, SOPs, or other documentation. The data quantification, validation, and review process can be verified during staff interviews. If laboratory procedures include documentation of the view and validation activities the assessor should select a representative data package (preferably samples analyzed for compliance purposes) to confirm that documentation of these policies exists.

3.1.6 Quality Assurance Officer

The laboratory must have a quality assurance officer who has defined (written) responsibilities for implementing the quality system. The quality assurance officer must have direct assess to management and be independent of the activities being monitored. The assessor should

- use the documents cited in Section 3.1.2 above to determine the role of the quality assurance officer at the laboratory.
- request records to verify that the quality assurance officer has the appropriate training and experience to perform this role.
- interview the quality assurance officer to verify the implementation of the defined quality assurance program.
- request records that will support the interview descriptions. These may include SOPs, sign-off sheets, or audit logs. (Note: audit reports are generally considered internal management tools and are “off limits” to assessors unless legal issues arise).

3.1.7 Inter-laboratory Comparisons

Participation in the proficiency testing (PT) program is a NELAC requirement. Prior to the assessment, the assessor should obtain the results of the latest PT results. The processing and analysis of PT samples should be reviewed during the assessment to determine if the data were

generated according to the methods required by the field of testing, that the data are traceable from the raw data, and that routine procedures were used to generate the results.

The laboratory may also be required to participate in intercomparison studies. This requirement should be identified prior to the assessment and verified during the assessment.

3.2 QUALITY SYSTEM

To determine if the laboratory has established and maintains a quality system appropriate to the type, range and volume of environmental testing activities it undertakes, the assessor must evaluate adherence to requirements throughout the entire audit process. A few isolated instances of inadequate documentation of the laboratory's quality assurance system and analytical quality control procedures would be an indication that the quality system is reasonably well documented. As the number of non-conformance increases, the probability of there being insufficient documentation of the quality system increases.

To determine if laboratory's quality system is adequately documented, the assessor must first evaluate the laboratory's quality documentation against the requirements of the NELAC Standards. This should be done as part of the assessment preparation phase. Quality documentation may include, but is not limited to, the quality manual, referenced standard operating procedures and work instructions, referenced analytical procedures, referenced health and safety procedures, organization chart(s), and job descriptions. It is important to remember that all quality documentation does not have to be included in the quality manual itself; however, all quality documentation must be referenced in the quality manual. While some of the quality documentation evaluation may be done on-site, in general, the on-site activities of the assessment should not be scheduled until the assessor is reasonably sure that the documented quality system meets the requirements of the Standard.

Either as part of the opening conference or immediately after the opening conference and on-site review of the documented quality system, the assessor should review any potential non-conformances in the documentation with the laboratory's management. The assessor should give the laboratory an opportunity to clarify any potential misunderstandings and present additional objective evidence prior to citing a non-conformance. The assessor must look beyond the "terms" used by the laboratory and evaluate the activities actually being performed. The assessor must remember that the laboratory may be required to meet multiple standards that use different terms to mean the same thing or use the same terms to meet different things.

As the assessor conducts the on-site assessment, the assessor must be constantly evaluating the activities being performed against the quality documentation. This is not only true for the evaluation of the quality system itself, but also during data review, technical analytical procedures review, and all other phases of the assessment. If the laboratory is performing quality activities that are not documented in the quality system, the laboratory should be given credit for performing the activity; however, the fact that the activity is not documented shall be cited as a

non-conformance. If the laboratory is performing an activity described in the quality documentation, but is not performing it in accordance with the documented instructions, the assessor shall cite the deviation as a non-conformance. If the laboratory is not performing an activity described in the laboratory's quality documentation the assessor shall cite the omission as a non-conformance. The assessor must then choose to use a combination of interviews and observations of personnel performing activities to determine actual performance and knowledge against documented procedures and requirements.

3.3 PHYSICAL FACILITIES - ACCOMMODATION AND ENVIRONMENT

It is a NELAC requirement that a laboratory have the physical capabilities required in the fields of testing for which it seeks NELAC approval. Documents received during the pre-assessment period should be reviewed by the assessor to become familiar with the laboratory's description of its facility. However, the adequacy of a facility must be verified during the on-site assessment.

The assessor will begin to evaluate the physical facilities during the tour of the laboratory that typically follows the opening conference. As the tour is conducted, the assessor should ask questions to identify the areas where activities associated with a field of testing occur. A map or floor plan will assist in this phase of the assessment because testing areas can be marked on the floor plan for future reference. During the tour, the assessor should be aware of the use of extension cords, fans, auxiliary air conditioners or heaters, lighting, posted notifications to workers, and general housekeeping that may indicate whether the facilities are adequate. The assessor must come to understand the flow of samples and standards from receipt, through storage, processing, archival, and final disposal. Assessors often accomplish this by asking that the tour be directed as if the assessor, him/herself, was a "sample" to be processed, or a "standard" to be prepared for analysis.

The detailed assessment of the physical plant will occur when compliance with field of testing methods are verified. Specific test methods will define the physical requirements for testing (temperature or humidity control, potential sources of cross-contamination, etc.). In addition, the laboratory's quality system document should define

- how the physical testing requirements will be monitored and documented,
- security of testing areas and how security is controlled,
- how appropriate housekeeping is accomplished, who is responsible, and how and where cleaning is documented.

The assessor must verify that the laboratory provides adequate

- space for testing
- separation of incompatible activities (e.g., glassware washing and VOA analysis)
- separation of samples and standards to prevent cross-contamination
- monitoring for potential contamination

- environmental control to meet the requirements of the test method
- records to document that the physical environment requirements of the test methods, QA manual, and standard operating procedures have been monitored and met, or that corrective action has been identified and implemented.
- security to ensure testing integrity
- access and entryways to the laboratory
- separate sample receipt and storage areas
- separate storage areas for chemical reagents and waste
- data handling and storage areas

The assessor should review logbooks used to document monitoring activities to determine if the laboratory is in compliance with its internal procedures. Verifying the "adequacy" of a facility may be subjective, however, and the assessor will most likely be aware of inadequacies rather than adequacies. For example, reviews of testing requirements vs. monitoring logs will document isolated vs. routine temperature excursions; repeated failure of negative controls in microbiological testing may indicate inadequate sterility. The assessor can verify his/her impressions during staff interviews by asking about power outages, temperature control, the integrity of testing areas, etc. The assessor has completed this phase of the assessment when it has been determined that

- the laboratory has a documented policy for providing a testing environment that is adequate,
- the laboratory practice is in compliance with its policy,
- the test method requirements are met,
- documentation is adequate to verify that testing is accomplished under the testing environment required by the method.

3.4 EQUIPMENT AND REFERENCE MATERIALS

3.4.1 Equipment

Each laboratory seeking NELAC approval for a field of testing must have, or have access to, all equipment required by the test method. The laboratory will typically provide an equipment list as part of the quality system manual or documentation. Prior to the on-site assessment, the assessor should prepare a list of the equipment that is required for each field of testing for which accreditation is sought. The required list can be compared to the quality system manual as a “first cut” assessment - all required equipment should be on the list. It is the responsibility of the assessor to verify during the assessment that the required measurement equipment is available, and that calibration and maintenance procedures are documented, current, traceable, and adequate.

During the on-site assessment each piece of equipment should be located and the documentation associated with the equipment examined. Separate records must be maintained for each piece of equipment. Equipment records must therefore refer to equipment uniquely - the manufacturer,

model, and serial number (or numbers, for equipment that is comprised of several components) is often used for this purpose. Instrument documentation must provide an operating history of the equipment. Records must include

- receipt and installation records
- the condition of the equipment when received
- the current location of the equipment
- the manufacturer's instructions
- dates and results of calibration or calibration verification
- scheduled calibration or calibration verification
- chronology of routine and non-maintenance
- history of damage, malfunction, modification, repair, and the results of verification testing

In order to determine that equipment is properly calibrated and maintained, the assessor must identify the method and laboratory requirements (SOPs, QA Manual), and then verify that the equipment is calibrated and maintained according to the site requirements and that these activities are documented. It should be possible to determine the calibration status of each piece of equipment during the assessment. Typically, calibrated equipment is labeled as such.

The assessor must also verify that the laboratory has written procedures for ensuring that malfunctioning equipment is identified and taken out of service. Reviews of maintenance records, corrective action logs, control charts, instrument logs or sample sequence files could contain references to instrument problems. The assessor should first ask what the laboratory's procedure is (how defective equipment is identified and labeled, and how problems are communicated to other staff to ensure that the defective equipment is not used) and where the procedure is documented. The assessor should then determine that the laboratory has procedures for verifying that instrument problems have not affected past calibrations or results, and what the policy is for client notification. Finally, the assessor should determine that the laboratory has a follow-up testing procedure and defined criteria to verify that equipment is operating correctly before it is put on line again. The results of verification must be documented.

In some cases the laboratory may not own the equipment used for testing. The requirements above also apply to rental or shared equipment.

3.4.2 Reference Materials

Test methods typically define reference materials required for instrument calibration, calibration verification, and quality control. The laboratory should have written procedures for tracking reference material receipt and for assessing the acceptability of these materials. The assessor must determine during the on-site assessment that these procedures are implemented and that the required materials are available and appropriate for use. Documentation of reference material receipt, expiration date, purity, lot, manufacturer, and storage conditions should be available. All materials should be labeled with an expiration date and no materials outside the expiration date

should be “on the shelf”. If the manufacturer or method does not define expiration dates and storage requirements, the assessor should verify that the laboratory has a written and implemented procedure for assigning expiration dates and storage conditions. Verification of reference material purity, stability, and/or concentration must be documented.

3.5 MEASUREMENT TRACEABILITY AND CALIBRATION

To determine if the laboratory’s system for measurement traceability and calibration meets the requirements of the standard, the assessor must evaluate adherence to requirements of the standard throughout the entire assessment process. A few minor isolated instances of non-conformances to the laboratory’s measurement traceability and calibration program would be an indication that the overall program for measurement traceability and calibration is adequate. Some examples of a minor non-conformance are:

Traceability: The laboratory does not maintain all of the records of the required certificates for its standards, however, all standards are in fact traceable as evidenced by the laboratory’s ability to obtain the required certificates with all of the required information as an Improvement action resulting from the audit. While there is a non-conformance (the laboratory does not maintain records of all certifications, NELAC Standard Section 5.9.2.b) it does not actually compromise the data in any way.

Calibration: Finding a calibration stock solution that is expired. However, the laboratory has empirical data (*e.g.* absorbance readings for AA) that show that the standard is, in fact, still within the manufacturers specifications, and the laboratory uses a second, independent check solution which is not expired and is in control. While there is a non-conformance (the standard is expired) the probability of the data being compromised is remote, if at all.

As the number and/or severity of non-conformances increases, the probability of the system for measurement traceability and calibration being inadequate increases. Some examples of a severe non-conformance:

Traceability: The laboratory does not maintain all of the records of the required certificates for its standards and upon further investigation it is determined that the standards being used are, in fact, not traceable to any nationally or internationally recognized standard reference material. There is a technical non-conformance to the standard (the standard reference materials are not traceable, NELAC Sections 5.9.2.a and 5.9.3.c), and as a result, the validity, quality, or usability of the data is compromised.

Calibration: Finding a calibration stock solution that is expired. In addition, the laboratory has no empirical data (*e.g.* absorbance readings for AA) that show that the standard is, in fact, still within the manufacturers specifications, and on further investigation it is determined that the empirical data is actually outside of the manufacturers specification. In addition to this, the laboratory does not use a second, independent check solution to verify its calibration solution. There are several

technical non-conformances to the standard (NELAC Section 5.9.3.b, 5.9.4.1.a, 5.9.4.2.1.c, and 5.9.4.3.a), and, as a result, the validity, quality, or usability of the data is compromised

3.6 TEST METHODS AND STANDARD OPERATING PROCEDURES

The laboratory must have documented procedures for the equipment use and operation, sampling handling, instrument calibration, and testing. This documentation can take several acceptable forms as long as the requirements of the standard are met. Documentation must be current and readily available to the staff using the procedures. Documentation is required for analytical methods, equipment, sample handling, general laboratory procedures, and record-keeping. Chapter 5 of the NELAC standard contains an exhaustive list with requirements associated with each; and the assessor must be familiar with these requirements. During the on-site assessment the assessor will verify that documented procedures exist, are adequate, are implemented, and that implementation is documented and traceable. The Chapter 5 checklist guides the assessor through the requirements.

3.6.1 Standard Operating Procedures

Assessment of the adequacy of the laboratory's SOPs may begin during the planning stage of the on-site assessment by making a list of the fields of testing for which accreditation is sought, the equipment required, and the supporting laboratory procedures that will be necessary to implement each method (*e.g.*, preparation of standards, data reduction, etc.). If the assessor can obtain a copy of the laboratory's SOP index or other descriptive document prior to the assessment he/she can identify and request copies of SOPs for review. If this is not possible, then the assessment must occur on site. The assessor must review each SOP to verify that it is adequate, that

- the level of detail is sufficient,
- the SOP procedures are consistent with the NELAC requirements,
- the SOPs include an approval signature, a revision number, and an effective date,
- the SOPs are logically organized, and that
- the SOPs are available to laboratory personnel

The last two requirements must be verified on site. In addition, while on-site the assessor must verify that any requirements described in the SOPs (calibration procedures and frequency, management reviews, records, etc). are implemented and documented according to the SOP.

3.6.2 Laboratory Method Manual(s)

The NELAC standard (Chapter 5.10.1.2) requires that the laboratory maintain a written description for the analysis of each accredited analyte or test. These are commonly kept in a "Methods Manual". Each procedure must be completely described along with any modifications to the methods. This documentation may be a copy of the current method, the method with documented modifications, or a laboratory SOP that describes the analytical method. If the method is vague

or offers more than one acceptable option, then the laboratory methods manual must a provide specific description of the procedure.

The assessor must ensure that the laboratory's written description of each procedure is consistent with any required methods and that the procedures are implemented according to the written procedures. This assessment may begin prior to the assessment but must be validated while on site. Ideally, the assessor should observe implementation of SOPs and analytical methods in the laboratory. If this is not possible good interview techniques will help to verify that the methods are being implemented. By "talking through" the method, the assessor can "walk" an analyst through the process. Leading questions such as "then what?, what happens next?, what if?" will provide a fair understanding of the process. Confirmation during subsequent interviews "what do you do to?" can corroborate interview information. Yes/No questions and the temptation to prompt or fill in the gaps must be avoided.

3.6.3 Test Methods

Each laboratory must demonstrate that it is accurately following any methods required for testing, or that if alternative methods (Performance Based Measurement Systems - PBMS) are allowable, that they are documented and validated. In addition to the test methods themselves, related testing activities (sampling, handling, etc) must be appropriate. The laboratory must have met the EPA method or PBMS requirements for an initial demonstration of proficiency as well as any required ongoing demonstrations of proficiency.

During the on-site assessment the assessor must review the documentation for these demonstrations, verify (to the extent possible) that the method procedures were followed, and that the method acceptance criteria for calibrations, quality control, and final proficiency results were satisfied. All supporting data required to reproduce the results must be available. The assessor should compare certification statements with instrument records and analysis reports to verify that staff performing the methods have successfully demonstrated proficiency in the method. During interviews with staff, the assessor should determine how analysts are selected for analysis of regulated samples, if the laboratory maintains a record of certified methods and analysts, or what other measures are taken to ensure that samples analyzed for regulated programs are analyzed according to required methods by certified staff.

3.6.4 Documentation and Labeling of Standards and Reagents

The laboratory must retain a written record of materials received for technical operations. The procedures for the purchase, receipt, handling, preparation, holding time, and storage of reagents, solvents, and standards must be documented. The preparation of reagents and stock solutions or dilutions thereof must be uniquely identified and be traceable to the original (neat) materials.

The assessor must verify that written records maintained for the receipt, preparation, and storage of chemicals used in testing is adequate to ensure that the materials were prepared accurately,

are traceable to their source, and were suitable for use. Through written descriptions in the QA Manual or SOPs and through interviews with staff the assessor will gain an overview of the laboratory's general procedures. To verify implementation of the policy, the assessor should choose selected calibration standards, spiking solutions, and reagents used for analysis and track them on paper from use, through preparation, to receipt. It should be possible to confirm through the use of proper documentation procedures and a unique identification scheme the

- preparation date and procedures
- the lot number and purity
- the expiration date and storage conditions
- the labeling requirements are fulfilled.

Unless the original material has been totally depleted, the assessor should request that the containers of dilution solutions, stock solutions, and neat materials be produced so that labels can be reviewed for completeness, compared to each other, to instrument and data records, and to receipt logs.

The calibration of some equipment will not generate an instrument printout or calibration curve. In these cases the assessor must verify that the calibration was performed using appropriate standards by reviewing the written calibration records. Calibrations must be performed using certified standards or equipment. For measurements such as weights, temperatures, and titrations, the standards used for calibration should be documented and traceable to certified values provided with the standard (*e.g.*, NIST-traceable thermometers). The assessor should verify that standards are traceable, within the appropriate range for the equipment being calibrated, and that any correction factors identified by the supplier have been applied.

3.6.5 Computer and Electronic Data Related Requirements

Laboratories increasingly rely on electronic data capture, reduction, and reporting capabilities. While these systems offer protection against simple transcription errors, they are not foolproof and must be operated in acceptable and consistent ways. EPA Document 2185, "Good Automated Laboratory Practices" (1995), Sections 8.1 B 8.11, must be implemented by laboratories seeking NELAC approval. The laboratory must have written procedures for the development, testing, documentation, and use of data-gathering, data-generating, and data-reduction software. Procedures for the development, testing, and use of electronic and automated equipment must be documented. Security provisions must be adequate to protect data integrity throughout analysis and reporting. The maintenance and environmental control requirements for software and supporting hardware must be defined.

The assessor must review the laboratory's written procedures for electronic media and verify that the requirements of the NELAC standard are adequately addressed. During the assessment the assessor must review laboratory records related to data-gathering or generating software to verify that the laboratory requirements have been implemented. Documentation and instructions for the

use of commercial products must be available to users as hardcopy or on-line help. (Note that it is typically difficult to receive testing information for standard commercial packages. In these cases the software output must be validated by the laboratory to verify operation and use). The laboratory must be able to demonstrate that security systems are adequate to protect data integrity.

3.7 SAMPLE HANDLING, SAMPLE ACCEPTANCE POLICY, AND SAMPLE RECEIPT

The laboratory must have documented procedures for how samples will be labeled, reviewed for acceptance, stored, and disposed. The procedures must produce an unequivocal paper or electronic trail.

Assessing the adequacy of these procedures is accomplished by first reviewing the laboratory's written procedures to determine their conformance to the requirements of the standard, and then, by reviewing how the laboratory actually performs the activities and the associated documentation and records. One effective technique for accomplishing this is to track an actual sample through the laboratory, and reviewing the associated documentation during the assessment. The assessor must verify that the laboratory's procedures are being implemented, that the activities are actually being performed in accordance with the written procedures, and are adequate to address the requirements of Section 5.11 of the NELAC standard. The assessment must include a review of the following:

- Sample receipt records
- Chain of custody forms (as required by the accrediting program)
- Assignment of laboratory IDs
- Storage records
- The storage area
- Records of storage area temperature conditions
- Any LIMS system used to log in or track samples
- Sample containers that have been "Received" and labeled

The assessor must verify that the laboratory is evaluating the condition of the samples upon receipt. When the laboratory receives samples that do not meet the sample acceptance criteria, the laboratory has two options.

1. The laboratory may reject the samples and retain all correspondences and records regarding the final disposition.
2. The laboratory may analyze the sample, noting the anomalous condition of the sample in accordance with requirements and must then qualify or "flag" the data on the final report.

It is critical that the assessor verify that one of these two these options is being performed when necessary. When the laboratory receives and analyzes samples where the results may be compromised, either legally or technically, due to the condition of the sample or the paperwork

upon receipt, it is essential that the data be qualified or “flagged” . Data flags are essential when samples do not meet acceptance criteria because they indicate to the data user that the data may not be traceable or may be compromised in some way. This information is essential for the data user to determine to what extent the data may be used, if at all.

Once the assessor is familiar with the laboratory’s procedures, there are tow techniques that can be used to “test” the system:

1. Track a sample, either forward or backwards, through the entire system. (Data in the public domain from either a state or federal program should be used) In this technique, the assessor would track the reported sample ID from the final report, through data reduction, analysis, processing, storage, and receipt and log-in [or forward (visa versa)].
2. If the assessor does not have access to public domain data, then a hypothetical sample should be tracked through the process.

In either case, the sample itself should be either retrievable or there should be documentation that the sample has been discarded in the appropriate waste stream. This process must be done on at least one sample in each field of testing for which the laboratory is seeking accreditation. Regardless of whether the assessor uses one of these two techniques or another technique, the assessor must document in the assessment report the method or technique used to verify system conformance to the standard.

An important element in the assessment is knowing the laboratory’s procedure for identifying aliquots, splits, dilutions, re-extracts, or other procedures that produce unique fractions and determining if sample fractions can be tracked. Each separate fraction or split of a sample must be uniquely identified so that it can be tracked specifically. (*e.g.*, the field sample ID may be assigned to separate containers targeted for trace metals, VOC, and PCB analysis.) The laboratory tracking procedures must be adequate to trace the life of each sample fraction separately. If the laboratory tracking procedures are not adequate to trace the life of each sample fraction separately, a non-conformance to Standard section 5.11.1 should be cited.

3.8 RECORDS

The laboratory must have documented systems for record keeping, records management and storage, sample tracking, and evidentiary chain of custody. The systems must be appropriate for the type of testing conducted, compliant with applicable regulations, and ensure that records are accurate, traceable, and retrievable.

The assessor may review the laboratory’s written procedures for the maintenance of records prior to the on-site assessment to verify that they meet the requirements of the NELAC standard; the quality systems checklist provides detailed assessment criteria. Once on site, the assessor must verify that the laboratory’s procedures are being implemented. The assessor must assess the laboratory’s written procedure, supporting documentation, and staff interview data in determining

whether the laboratory is following its own procedures and whether those procedures meet NELAC requirements for

- The record-keeping system
- Records management and storage
- Sample tracking (handling, support activities, analytical records, and administrative records)
- Legal or evidentiary custody

One of two methods are typically employed for these assessment. The first approach is to select each component of the records system individually and investigate the laboratory's procedure and practice through interviews and observation of records and practice. The second approach is to select one or more data reports as a vehicle, and verify the records management system by tracking the data and supporting documentation through the process. The approach used will depend on the size of the assessment team, the size of the laboratory, and the number of fields of testing for which approval is sought. The assessor should request:

- sample receipt, preservation, storage, and preparation records - these should be adequate to track sample handling and processing.
- raw data records related to the reports - these should be readily available; proper data recording procedures should be observed; original (hardcopy) instrument calibration records and certificates of analysis - the analyst should verify that the laboratory retains these original records in a systematic, identifiable, secure manner.
- data tapes and demonstration that the hardcopy data and electronic versions are identical - the assessor can also take this opportunity to review manual modifications (integration corrections, etc) to the instrument results with the analyst; verify that electronic data are backed up as hardcopy or as write protected electronic data, and stored securely.
- personnel records for analysts - a comparison of dated training and experience records should be sufficient to verify that the analyst was qualified to conduct the work.
- SOPs in use at the time of analysis - current SOPs should be readily available, the assessor should verify at this time that previous versions of SOPs are maintained.

During the review of documentation the assessor must be aware of improper documentation procedures: back-dating, filling in gaps, documentation by staff other than those conducting the work. Because most laboratories may increase diligence in the weeks preceding an assessment, the records for the previous 6 months should be reviewed to identify documentation patterns and practices. The assessor should be aware of

- Uneven levels of detail in maintenance and calibration logs - detailed and frequent information in recent weeks and spotty documentation previously.
- Information that looks "too neat," entered using the same type of pen and hand-writing but purportedly entered over several days/weeks.
- Information documented by supervisors rather than the personnel who performed the work, unless SOPs specify that supervisors are responsible for specific types of documentation.

- Photocopies of records that do not agree with originals

In order to verify that routine sample tracking records are adequate, the assessor should be able to track the samples from receipt and initial preservation, through processing and analysis, to archival and, if appropriate, disposal. All data used in the generation of reported values should be documented and traceable. Review, validation, and reporting activities should be documented (verifiable) and consistent with laboratory policy.

The assessor should request a tour of the laboratory's data archive to verify that the area is secure, that access is limited and documented, that the environment provides adequate protection. The laboratory must have documented procedures for the maintenance of project records that meet NELAC requirements, and should be able to demonstrate compliance with those requirements. The assessor must use care in the review of these records to respect client confidentiality issues.

For some clients or programs, legal or evidentiary chain of custody protocols may be required. The laboratory must have a written procedure for maintaining legal chain of custody of samples. The assessor can verify the existence and adequacy of this document prior to the assessment. The implementation of the procedures must be verified during the on-site assessment. By definition, sample custody must be documented and traceable at all times defined by the program (this may start with the preparation of sample containers for collection, at collection, or when samples are received at the laboratory). The assessor must carefully review the custody records against the requirements of the standard to verify that the conditions are met. Staff interviews are an essential part of this assessment. How information is documented, when information is recorded, who records the information, where custody records are kept prior to processing, during processing, and after processing is critical. The process of interview and review of records should enable the assessor to determine compliance or non-compliance with the standard. In addition, the assessor must verify that requirements for controlled access are met. This is accomplished through inspection of the space allocated for the custody room, and interviews with staff to determine the restrictions to access that are implemented for COC samples.

3.9 SUBCONTRACTING ANALYTICAL SAMPLES

The laboratory may not subcontract the analysis of samples for accredited fields of testing without notifying the client that sample analysis will be subcontracted, verifying that the subcontractor laboratory is accredited under NELAP, and retaining records demonstrating that these requirements were met.

The assessor should first determine whether the laboratory has a written policy for the selection and use of subcontractors. During the assessment interviews the assessor should ask management under what circumstances subcontractors are used for analysis, how subcontractors are selected, and how and when the client is notified. The use of a subcontractor that is NELAP accredited is acceptable as long as all required documentation is maintained with the data. The

use of subcontractors may be evidenced by

- Sample identification numbers that do not match the laboratory's numbering scheme
- Analysis dates that conflict with instrument run logs
- Data that cannot be tracked internally
- Letters of transmittal from the laboratory or letter reports from a subcontractor laboratory

3.10 OUTSIDE SUPPORT SERVICES AND SUPPLIES

The laboratory may use outside services and supplies that are not specifically regulated by the NELAC standards. However, the laboratory is accountable for the quality of those services and supplies and must have procedures to verify confidence that testing quality is uncompromised by the use of unregulated materials and activities.

The assessor should

- verify that the laboratory has a written procedure to ensure the quality of products and services. This may include independent testing, inspection, or validation.
- Review records to assess compliance with internal policy,
- Determine that the review and inspection is adequate to ensure quality
- Verify with staff that the procedures are implemented according to the laboratory's policy.

3.11 COMPLAINTS

To determine if the laboratory's system for handling complaints meets the requirements of the standard, the assessor must evaluate adherence to requirements of the standard primarily during the document review and evaluation of the quality system phases of the assessment. The assessor should evaluate how complaints are received, recorded, and how follow up action is handled and recorded through the final resolution of the complaint. The assessor must determine if there is criteria for prompting an audit in accordance with section 5.16 and 5.5.3.1 of the standard, and if there is criteria for prompting the laboratory to notify clients in accordance with section 5.13.e of the standard. The assessor must verify that the procedures for these activities are documented and that records of these activities are maintained.

The Assessor must be aware of the difference between a complaint and the handling of routine questions regarding data. While the laboratory should have a procedure for handling questions about data (reviewing data, rerunning the sample, etc.), routine questions regarding data should not be considered complaints unless some abnormal event occurs such as a sample that is rerun is not within the method uncertainty limits. Routine questions about data, that do not become complaints, need not prompt an audit in accordance with section 5.16 and 5.5.3.1 of the standard or prompt the laboratory to notify clients in accordance with section 5.13.e of the standard.

CHAPTER 4
BASIC AUDITING SKILLS

4.1 Standards of Ethical Conduct

NELAC assessors must adhere to the following general standards for ethical conduct:

1. Assessors shall put forth honest effort in performance of their duties.
2. Assessors shall act impartially and not give preferential treatment to any organization or individual.
3. Assessors shall provide equal treatment to all persons and organizations regardless of race, color, religion, sex, national origin, age, or handicap.
4. Assessors shall not use their position for private gain.
5. Assessors shall not solicit or accept any gift or other item of monetary value from any laboratory, laboratory representative or other affected individual or organization doing business with or affected by the actions of the assessor's employer or accrediting authority.
6. Assessors shall not hold financial interests that conflict with the conscientious performance of their duties.
7. Assessors shall not engage in financial transactions using information gained through their positions to further any private interest.
8. Assessors shall not engage in employment or activities, including seeking or negotiating for employment, that conflict with their duties and responsibilities as assessors.
9. Assessors shall not knowingly make unauthorized commitments or promises of any kind purporting to bind their organizations or accrediting authorities.
10. Assessors shall endeavor to avoid any actions creating the appearance that they are violating any of the standards for ethical conduct applicable to NELAC on-site assessors.

These standards are based on the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR 2635), which apply to employees of the Federal government. State governments typically utilize similar standards of conduct to govern their employees. Consequently, it is anticipated that NELAC assessors who are employees of state or Federal government organizations will be familiar with and already practicing similar standards of conduct. The Standards of Ethical Conduct for NELAC Assessors apply to all NELAC assessors, however, whether government employees or employees of third party organizations conducting NELAC assessments under an agreement with a NELAP-approved accrediting authority.

For purposes of interpreting standards #6 and #8, a conflict of interest is defined as a relationship with an entity that may impair the objectivity of the assessor in performing his or her responsibilities. Most state and Federal government organizations should have policies requiring that employees report outside activities that might constitute a personal conflict of interest. Personal conflicts of interest may also arise and must be carefully monitored in programs where third party organizations are used to conduct on-site assessments. In such cases, assessors who are employees or are working under contract to the third party organization may be required to

disclose any potential conflicts of interest on a periodic basis, when they become known, and/or prior to making staff assignments for individual laboratory assessments.

4.2 Confidentiality of Information

Section 3.4.5 of the NELAC standards addresses Confidential Business Information (CBI) considerations in conducting on-site assessments. This section requires that:

- Assessors provide a confidentiality notice to laboratory representatives at the start of each on-site assessment to inform laboratory officials of their right to claim information as CBI;
- Assessors and any others who may have access to CBI resulting from on-site assessments be trained in proper procedures for handling CBI;
- Assessors be familiar with procedures for asserting a claim of CBI;
- Assessors take possession of all CBI documents at the close of an on-site assessment and retain custody of the documents until the designated official at the accrediting authority is assigned custody of the documents;
- Laboratory officials mark all documents claimed as CBI, either with a cover page or a stamp on the first page indicating that the document is “trade secret”, “proprietary”, “company confidential”, or other suitable designation;
- All CBI documents be held in a secure manner by the accrediting authority and not distributed.

The standards also make the following key points:

- Claims of CBI may be made after the on-site assessment by notifying the accrediting authority. In such cases, the accrediting authority may not be able to assure that disclosure has not occurred.
- On-site assessors are not responsible for making any determinations with respect to the validity of any CBI claim.
- Laboratories must be notified in writing in the event that the accrediting authority determines that a CBI claim is not warranted and proposes to declassify it.

In cases where the accrediting authority challenges a CBI claim, the laboratory must be notified of the challenge and allowed 15 working days to do one of the following:

- Address the challenge by providing written justification of the CBI claim;
- Propose a resolution to the issue in a manner that is suitable to both parties;
- Determine whether to pursue administrative or legal relief; or
- Withdraw their application for NELAC accreditation.

In most cases, accrediting authorities will have training programs, policies, and administrative and functional operating procedures for handling CBI, which will be utilized by on-site assessors. It is anticipated that these programs will be substantially similar to those used by EPA programs.

4.3 Gathering Objective Evidence

4.3.1 Observation

One effective method for gathering objective evidence is through observation. The assessor should, wherever possible, observe analysts performing analyses. Assessors should also note the general housekeeping practices of the laboratory, as poor housekeeping practices could indicate the potential for cross-contamination.

There are also some areas to be assessed that can really only be performed through observation. These areas include, but are not limited to: verifying labeling practices, checking for proper class of calibration weights, etc.

4.3.2 Staff Interviews

During the detailed assessment of laboratory work areas, assessors should begin asking questions of the staff. In general, questions should be probing and not leading, and assessors should avoid asking questions with simple yes/no answers. Assessors should encourage staff to elaborate by being attentive, patient and interested. All of the principles that apply when conducting staff interviews should be utilized when speaking informally in the laboratory.

Formal staff interviews should be planned and scheduled in advance, if possible. The lead assessor should arrange with the laboratory that adequate and appropriate office space will be made available for conducting private interviews. Assessors should employ good interviewing techniques and should be prepared to ask probing questions and to rephrase questions if necessary to receive a satisfactory answer. Assessors should maintain neutral body language so as not to provide visual cues that lead the respondent toward certain answers. Throughout the interview, assessors should make note of follow-up and other questions to ensure that they are not forgotten.

The following methods should be utilized in conducting interviews:

4.3.2.1 Planning the Interview

- Address all logistics such as time, duration, and location.
- Ensure privacy and confidentiality.
- Define the desired outcomes for each interview.
- Organize your thoughts and establish a general sequence for questioning.
- Practice on a colleague, if necessary.

4.3.2.2 Interview Setting

- Ensure that the respondent feels that there is sufficient privacy.
- When appropriate, conduct discussions in the respondent's work area.
- Interviews should be "one-on-one".
- Minimize potential distractions.

4.3.2.3 Conducting the Interview

- Establish rapport. Ask simple questions or verify information that has been given already (educational background, years in present position, comments concerning respondents interest/hobbies, if known) before moving into the more pertinent interview material.
- Request a brief overview of the respondent's responsibilities in the laboratory.
- Ask open-ended questions (i.e., "how" or A"hat" questions) rather than obvious yes/no questions (i.e., "Do you..." questions).
- Ask follow-up questions where answers are unclear or incomplete. Remember, you may need to ask the same question several different ways to get the information needed.
- Avoid making assumptions.
- Avoid leading questions or body language.
- Provide feedback to the respondent as appropriate, to encourage complete answers.

- Tolerate silences in order to allow the respondent to formulate thoughts and responses.
- Do not expect any one person to have complete knowledge. Talk to others.
- Do not get sidetracked in areas outside the scope of the assessment, such as regulatory policy or the relative effectiveness of methods.
- Beware of the chronic complainer or lobbyist. These individuals may attempt to use assessors to advance their complaints to management.
- Avoid jumping too quickly to conclusions during an interview. Get all the facts, including views from other people, before concluding that a deficiency exists.
- Do not become part of the laboratory's problem. Remain detached and professional.
- Do not accept the staff's word about a specific situation. Seek objective evidence and make an independent professional judgement.

4.3.2.4 Interpersonal Considerations

- Shake hands.
- Maintain appropriate eye contact.
- Maintain appropriate distance.
- Use appropriate voice tone and inflection.
- Do not jump to conclusions.
- Make sure the respondent has finished speaking with each response. Do not complete the respondent's sentences.

4.3.2.5 Closing the Interview

- Do not exceed the established time limit without the respondent's consent.
- End on a positive note.
- Summarize your understanding of key points to ensure accuracy.

4.3.2.6 Documenting the Interview

- Record the context of the interview (time, date, name and position of respondent).
- Make notes of key points during the interview; do not attempt to record a verbatim transcript.
- Take a few minutes to summarize the outcome of the interview before beginning the next interview.

4.3.3 Exhibits

Exhibits are the tangible evidence the can be assessed. These include logbooks and other documentation. These items could be copied, if necessary, to support the assessment.

4.4 Role of the assessor in interpreting assessment results

The assessor is a fact-finder, not a decision maker. His/her role is to observe and note the extent to which the laboratory meets applicable standards, not to judge the adequacy of the laboratory. Near the end of an on-site assessment, the lead assessor should meet with the team to identify all of the deficiencies found and review the observations and objective evidence supporting each. Together, team members should determine whether the evidence gathered indicates any deficiencies.

Assessors should strive to maintain an informed, professional, and objective demeanor at all times. ANSI makes the following statement concerning important attributes for assessors:

> *Assessor candidates should be open minded and mature, possess sound judgement, analytical skills, and tenacity; have the ability to perceive situations in a realistic way, to understand complex operations from a broad perspective, and to understand the role of individual units within the overall organization.*

ANSI further identifies a list of responsibilities that assessors should fulfill, including:

- Obtaining and assessing evidence fairly;
- Remaining true to the purpose of the assessment without fear or favor;
- Constantly evaluating the effects of observations and personal interactions during an assessment;
- Treating concerned personnel in a way that will best achieve the assessment purpose;

- Performing the assessment without being distracted;
- Committing full attention and support to the assessment process;
- Reacting effectively in stressful situations;
- Arriving at conclusions that are supported by observations and evidence; and
- Remaining true to a conclusion despite pressure to change that is not based on evidence.[2]

Throughout the assessment, the assessors' chief priority is to preserve the integrity of the assessment by maintaining objectivity and ensuring complete and reliable documentation.

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[2] See *Guidelines for Auditing Quality Systems - Auditing,* ANSI/ASQC Q10011-1-1994.

CHAPTER 5
ASSESSMENT PRINCIPLES AND PRACTICE

5.1 Approved Training

This manual and related training materials serve as the basis for all approved assessor training courses. There will be a written examination given upon the completion of this course.

5.2 Pre-Assessment Procedures

Thorough planning and preparation prior to conducting an on-site assessment ensures that the assessment will be as efficient and effective as possible. In general, planning activities will be the responsibility of the lead assessor assigned by the Accrediting Authority.[3] All members of the assessment team must be involved in planning the assessment, however, to ensure that they are well-prepared and can function independently while at the laboratory.

Exhibit 5-1 summarized the pre-assessment planning process, which consists of four principle steps: 1) scoping, 2) staffing, 3)scheduling, and 4) work plan development. The exhibit identifies the parties responsible for each step in the process, the information needed to complete the step, and the outcome of each step. The final outcome of pre-assessment planning is a work plan for the assessment which identifies the assignments for all members of the assessment team; lays out a complete schedule of activities for milestones; and sets target dates for all activities through finalization of the assessment report and archiving of the assessment records.

[3]The processes for planning and conducting an on-site assessment presented in this manual are designed for an analytical laboratory seeking accreditation in multiple fields of testing involving analytical methods from several different disciplines. Such assessments are likely to require a team of assessors. In many cases, the scope of the application for accreditation of staffing limitations will dictate that an assessment be conducted by a single assessor. In these cases, all of the functions identified for the assessment team will be the responsibility of the lead assessor.

EXHIBIT 5-1
Summary of Pre-Assessment Planning Activities

Step	RESPONSIBLE PARTY	INFORMATION REQUIRED	OUTCOME
1. Scoping	Lead Assessor	Application for accreditation or renewal of accreditation	List of fields of testing and methods for which the laboratory seeks or has previously attained accreditation.
2. Staffing	Lead Assessor	Scope of assessment COI certification	Assessment Team
3. Scheduling	Lead Assessor Director (however named) Assessment Team	Scope of assessment Staffing plan	Agreement on dates of assessment Schedule of events
4. Work plan	Assessment team	Application for accreditation or renewal of accreditation Report from most recent on-site assessment Most recent PT results Other information specified by Section 3.4.3 of the Standard	Team assignments Assessment work plan

5.2.1 Define the Scope of the Assessment

For all routine assessments, the lead assessor should begin the planning process by creating a master file for the assessment records and obtaining a copy of the laboratory's application for accreditation or renewal of accreditation. The application should identify the fields of testing and analytical methods for which accreditations sought. This information will allow the lead assessor to obtain the appropriate checklists for conducting the on-site assessment. The lead assessor should be careful to verify the analytical methods identified in the application and should ensure that reference copies of all methods are available to the assessment team for use throughout planning, conducting, and reporting on the assessment.

The scope of a non-routine assessment will depend on the purpose of the assessment. If it is to be comprehensive, a similar examination of the laboratory's most recent application or

accreditation certificate should be made to identify the fields of testing and analytical methods for which the laboratory is certified. The scope of a non-routine assessment that is targeted to address a specific problem will be defined by the recent history of the laboratory and/pr any agreements concerning corrective action that have been made.

5.2.2 Select the assessment team

Once the lead assessor has defined the scope of the assessment, a decision can be made concerning the need for additional assessors. In general, assessments should ve conducted by at least two qualified assessors. This will ensure that a second professional opinion is available to validate conclusions and will protect assessors from unwarranted allegations of bias. In many cases, however, accrediting authorities may not have sufficient staff to assign two assessors to each laboratory; or, in the case of a small laboratory seeking accreditation for only a limited number of analyses, assigning two assessors may not be necessary.

Upon making initial staff selections, the lead assessor must obtain a signed Conflict of Interest (COI) certification from each assessor to be included on the team. Refer to section 4.1 of this manual for guidance on conflict of interest and criteria for identifying an actual or potential conflict of interest. An assessor who has a real or apparent conflict of interest is ineligible to participate on the assessment team.

5.2.3 Schedule the assessment

For announced assessments, the lead assessor should contact the laboratory's director (however named) and identify mutually acceptable dates for the assessment. They should agree on:

- The date and time at which the assessment team will arrive at the laboratory;
- The date and tentative time at which the assessment team will leave the laboratory; and
- The date on which the laboratory will receive the draft assessment report.

During this conversation, the lead assessor should be prepared to identify the members of the assessment team and discuss the scope of the assessment, as allowed by the policies of the accrediting authority. Following the conversation, the lead assessor should provide written verification of the agreement in the form of a letter which announces the assessment and the mutually accepted schedule.

At this point, the lead assessor should contact the assessment team to discuss the following:

- Ensure the availability of all assessors;
- Agree on all team members assignment for all phases of the assessment process;
- Agree on a schedule with the elements summarized in Exhibit 5-2;
- Agree on team member roles and responsibilities for work plan development

EXHIBIT 5-2
Elements of the On-Site Assessment Schedule

1. Schedule for work plan completion:
   - Date for completion of draft work plan
   - Review/approval process and dates
   - Date for completion of final work plan

2. Dates of the on-site assessment

3. Final report schedule
   - Date for completion of first draft
   - Review/approval process and dates
   - Date for completion of revised draft
   - Target date for approval and release to laboratory
   - Target date for final report

5.2.4 Develop the assessment plan

Accrediting authorities may utilize standard operating procedures and/or templates for developing assessment work plans. Such tools make the work plan development process efficient and ensure that work plans are complete and effective. At a minimum, the assessment work plan should:

- Define the scope of the assessment in terms of testing, analytical methods, checklists or other terms as appropriate;
- Identify the laboratory processes to be evaluated:

  Laboratory organization and management
  Quality system
  Personnel and staffing
  Physical facility
  Equipment maintenance
  Sample handling, acceptance and tracking
  Records management
  Reporting
  Subcontracting
  Procurement of supplies and services
  Handling of customers' complaints

  and assign team members to their review according to expertise;
- Identify the analytical procedures to be evaluated and assign team members according to expertise;

- Identify the extent to which a records review will be conducted (in accordance with section 3.4.2.2 of the NELAC standards) and assign team members according to their expertise;
- Identify the background material reviewed by the assessment team;
- Identify documents to be requested from the laboratory;
- Define an agenda, including dates and times for all activities to be conducted during the assessment, and assign team members as appropriate;
- Schedule private meetings of the assessment team to occur during the assessment;
- Identify, to the extent possible, laboratory staff to be interviewed during the assessment and team members who will conduct the interviews.

In order to complete the work plan, members of the assessment team should review the documents identified in Exhibit 5-3. At a minimum, prior to beginning work plan development, assessors should review the laboratory application, the final report from the laboratory's mos recent on-site assessment, and the laboratory's most recent proficiency testing results.

EXHIBIT 5-3
DOCUMENTS TO BE REVIEWED PRIOR TO N ON-SITE ASSESSMENT IN ACCORDANCE WITH SECTION 3.4.3 OF THE NELAC STANDARDS

Copies of previous assessment reports and proficiency testing results

General laboratory information such as self-assessment forms submitted by the laboratory, SOPs, and quality manuals

Official laboratory communications with accrediting authority staff and associated records (*e.g.*, previous corrective action plans)

Available documents from recipients of laboratory reports

Current program regulations and special requirements that apply to the fields of testing or analytical methods for which the laboratory seeks accreditation (*e.g.*, security clearance requirements, radioactive exposure protocols, etc.)

Current versions of the analytical methods used by the laboratory to conduct the tests covered by the accreditation.

At a minimum, the work plan should be reviewed and approved by each member of the assessment team. Individual accrediting authorities may have standard operating procedures applicable to work plan development which involve management review and approval as well. Also, at the discretion of the accrediting authority, portions of the work plan may be provided to the Laboratory Director (however named) in advance of the assessment. At a minimum, the Laboratory Director should be provided with an agenda for the assessment and a list of documents or records, if any, to be produced for the assessment team. The accrediting authority may or may not choose to identify staff to be interviewed prior to arriving at the laboratory.

5.2.5 Preliminary Analytical Record and Data Review

An assessor may choose to obtain copies of analytical records and data from a laboratory before an on-site assessment. Obtaining certain analytical records and analytical data before an assessment *e.g.*, run logs or MDL summary sheets, can help the assessor plan for the data audit portion of the assessment. This preplanning can save many hours of time for the laboratory and assessor. By reviewing the run logs, an assessor can tell the laboratory before the assessment which chain-of-custody records, hard copy data packets and electronic data (if applicable) to have available for review during the assessment. Obtaining full data packets before an assessment may not be viable due to the shear volume of the data from certain types of analyses.

5.3 Handling Confidential Business Information (CBI)

In accordance with section 3.4.5 of the NELAC standards, the lead assessor must notify the laboratory director (however named) of the laboratory's right to claim that information provided during the assessment is Confidential Business Information (CBI). During the assessment, the assessment team is not responsible for making any determinations with respect to the validity of any CBI claim. All information so designated should be appropriately marked, by the laboratory staff or the lead assessor, and handled accordingly. During the assessment, the lead assessor should assume the responsibilities of a document control officer. Consequently, the lead assessor must be trained in procedures for handling CBI. All members of the assessment team should also be familiar with CBI requirements. Any information identified as CBI during the assessment should be safely transported back to the accrediting authority, received, and handled consistent with the accrediting authority's CBI program. Additional discussion of CBI concerns during on-site assessments is presented in section 4.2 of this manual.

5.4 Assessment Procedures

Section 3.5 of he NELAC standards specifies that all on-site assessments consist of the following elements:

- An opening conference;
- Records reviews;
- Staff interviews; and
- A closing conference.

5.4.1 Opening Conference

The purpose of opening conference is to introduce the assessment team and identify key laboratory personnel, review the purpose of the assessment and the schedule of activities, understand any special requirements that the laboratory may have (*e.g.*, requirements related to health and safety or confidentiality of information), and allow the laboratory director (however named) to answer any questions necessary to understand the assessment process and events

that will follow the assessment. During the opening conference, the lead assessor should discuss CBI concerns. The opening conference should also include a walk-through of the laboratory, as discussed previously. Exhibit 5-4 identifies topics that must be addressed at the opening conference, in accordance with section 3.5.2 of the NELAC standards. It is important to note that the standards specifically state that assessor should never, under any circumstances, sign a waiver of responsibility on the part of the laboratory for injuries incurred by a team member during an assignment in order to gain access to the laboratory.

EXHIBIT 5-4
REQUIRED TOPICS FOR THE OPENING CONFERENCE

1. The purpose of the assessment

2. Introduction of the assessment team

3. Tests that will be examined

4. Any records and operating procedures to be examined during the assessment and the names of the individuals in the laboratory responsible for providing the assessment team the necessary documents

5. The roles and responsibilities of key managers and staff in the laboratory

6. Confidential Business Information handling procedures

7. Any special safety procedures that the laboratory may require firth protection of the assessment team while in the facility

8. The standards that will be used by the assessors in judging the compliance status of the laboratory operation

9. Confirmation of the tentative time for the closing conference

10. Presentation and discussion of the assessment appraisal form and its purpose

11. Discussion of any questions the laboratory may have about the assessment process

5.4.2 Assessing laboratory conformance

5.4.2.1 Analytical Records and Data Review

An essential part of any NELAC on-site assessment is performing an analytical records and data review of the laboratories testing. The analytical records and data review should include all laboratory documents tracking a particular sample from laboratory receipt to the final laboratory reporting of the sample testing results.

The analytical records and data review will vary widely depending on the field of testing that is being assessed. Analytical records can vary from simple hand-written transcriptions by an analyst of observations in microbiology and wet chemistry analyses to more complex computer print-outs of chemical absorptions, chromatograms, or mass spectra. In general however, all data should be evaluated by an assessor from its rawest form to determine method compliance and scientific defensibility.

An example of this review for organic chemistry analyses would include a review of chain-of-custody documents, extraction records (if applicable) and sample analysis records of testing from instruments to determine if sample holding times had been met by the laboratory. Once this is determined, a review of the hard copy calibration, method and sample data packet records should be reviewed for conformance with the NELAC standards and methodology. An electronic computer data review should be completed if the hard copy data that was reviewed was unclear or had apparent discrepancies. Once the analytical data has been adequately reviewed, the assessor should then follow the data results through any data input system to the production of the final report. The final report would then be reviewed for accurate reporting of chain-of-custody information and analytical results.

5.4.2.2 Records Review

Records reviews may be conducted for two purposes:

- To verify the efficacy of laboratory processes; or
- To verify data recording, calculation, reduction and reporting activities

Exhibit 5-6 shows the minimum elements of a record set to be examined during an assessment, as required by section 3.5.3 of the NELAC standards.

EXHIBIT 5-6
MINIMUM REQUIRED RECORD SET TO BE EXAMINED DURING A NELAC ON-SITE ASSESSMENT

1. Application for accreditation submitted by the laboratory	9. Documentation of the origins, purities, assays, and expiration dates of primary standards, analytical reagents and standard reference materials
2. Previous assessment results and reports, including PT results	10. Records associated with method specific quality control requirements
3. Laboratory management structure and chains of responsibility (*i.e.*, organization chart)	11. Records associated with the initial method validation study associated with each method for which the laboratory seeks accreditation, to be examined in detail with the historical calibration data
4. Qualifications statements for all key staff involved in the analysis or reporting of results and records demonstrating how key staff fulfill the qualifications requirements of their positions	12. Records associated with the methods used to estimate precision and accuracy in general for specific analyses
5. Quality assurance plan(s)	13. Sample receipt and handling documentation
6. Standard Operating Procedures and method protocols for each parameter for which accreditation is sought	14. Proficiency testing sample receipt and handling procedures
7. Maintenance and calibration records for specific equipment separate fro those included in measurement records	15. Information about the proficiency testing provider(s) used by the laboratory
8. Records for the preparation and calibration of stock solutions and standard reagents	16. Records of any internal audits conducted or corrective actions taken by the laboratory
	17. The documentation of the laboratory's annual management review

5.4.2.3 Staff Interviews

Staff interviews should be scheduled and planned, in terms of topics to be covered, in advance.

The laboratory director may be given a list of staff to be interviewed before the assessment team arrives at the laboratory or at the opening conference. The lead assessor may establish a schedule for interviews, or allow the laboratory director to prepare a schedule based on staff availability. Assessors should recognize that if staff to be interviewed are identified in advance of the assessment, the laboratory director will be able to be more responsive to schedules established by the assessment team. Identifying staff to be interviewed prior to commencing the assessment has the drawback of allowing additional time for staff to prepare for interviews, however. Additional guidance on conducting interviews is provided in section 4.3 of this manual.

5.4.2.4 Closing Conference

Upon completion of the assessment, the assessment team must conduct a closing conference to inform the laboratory director of any deficiencies identified. The assessment team should endeavor to be as complete as possible in its identification of deficiencies. Any information or conclusions that would support enforcement actions, however, should not be discussed, unless explicitly authorized by the Accrediting Authority. Before adjourning, the lead assessor should review items that have been claimed to be CBI, review the schedule for completing the assessment report, and inform the laboratory director of procedures for responding to the assessment findings, which include:

- Submitting a plan of corrective action, followed by an additional on-site assessment for verification purposes (if necessary); or
- Requesting a review of the assessment in accordance with the provisions of Chapter 4 of the NELAC standards.

The closing session should reflect the fact that the purpose of the assessment is to judge the extent to which the laboratory is in compliance with the NELAC standards, not to pass judgement on the overall quality of the operation. Consequently, the closing session should always be conducted in a factual and positive manner.

5.5 Reporting and record-keeping

5.5.1 Reports

Although reporting actually begins during the closing conference when the lead assessor presents a summary of the assessment findings, the final product for the assessment is a formal, written report. Consistent with section 3.7.2 (report format) of the NELAC standards, the final report for an on-site assessment should be written in narrative form and should describe existing conditions at the laboratory and identify and describe any deficiencies. At a minimum, the report must include:

- Identification of the laboratory (name and address);
- Date or dates of the assessment;

- Identity and affiliation of each member of the assessment team;
- A statement of the objectives of the assessment, including correction of prior deficiencies, if applicable;
- A summary of conditions at the laboratory;
- Documentation of the findings resulting from the assessment (including a description of all deficiencies found and a summary of the objective evidence supporting the findings); and
- Comments and recommendations.

All deficiencies described must be described in the context of the applicable NELAC standard or appropriate test method, and the specific standard (section number and text) must be cited.

The final report must be completed and transmitted to the laboratory within 30 working day following completion of the on-site assessment. Information from the report concerning the results of the assessment and the laboratory's status must also be forwarded to NELAP for inclusion in the NELAC database. The report deadline may be delayed in cases where the accrediting authority has cause to conduct further investigation of conditions or practices at the laboratory, or is taking another action related to the accreditation status of the laboratory. In such cases, the accrediting authority must notify the laboratory of the proposed date for completion of the report and of the cause of the delay.

All on-site assessment reports are eventually made available to the public upon request. In accordance with section 3.7.5 of the standard, reports will be made available first to the laboratory director (however named). The laboratory director must be allowed to request clarification regarding any aspect of the report and may take exception to any findings reported by notifying the accrediting authority in writing within 15 working days following receipt for the report. Once any issues are resolved, the on-site assessment report must be finalized and transmitted to the laboratory and NELAP. Reports cannot be released to the public until they are final. In accordance with Freedom of Information laws, any information judged to be proprietary, financial and/or trade information, or relevant to an on-going enforcement investigation is exempt from public disclosure requirements.

5.5.2 Records

Upon completion of the final report from each on-site assessment, the assessor or lead assessor should ensure that a complete file containing all of the original records of the assessment, is compiled and stored according to the standard procedures specified by the accrediting authority. The file should include:

- A list of any documents reviewed by the assessor(s) prior to conducting the on-site assessment (such as the application for accreditation, reports of laboratory performance on recent proficiency tests; quality system manuals, laboratory methods manuals, reports from previous on-site assessments, or other documents). Either the location of each document should be noted on the list or a copy of the document should be included in the

file.

- Copies of correspondence between the accrediting authority and laboratory officials, and correspondence between the accrediting authority or lead assessor and members f the assessment team (including certification concerning personal and/or organizational conflict interest) generated prior to or following the on-site assessment.
- Written entries documenting telephone conversations with laboratory officials pertaining to the on-site assessment or corrective action following the on-site assessment.
- The original on-site assessment check-lists completed during the assessment (also completed in ink).
- Any photographs (and negatives) and/or audio or video tape recordings made during the assessment.
- All copies of laboratory records made by members of the assessment team or provided by laboratory officials.
- The final version of the assessment report.
- The corrective action plan, if any, submitted by the laboratory and any related correspondence or written comments.

Files should be archived in accordance with the procedures established by the accrediting authority. In accordance with section 3.7.6 of the NELAC standards, on-site assessment files must be maintained for a period of five (5) years, or longer if required by state statue or Federal regulation.